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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/570,252

03/02/2006

Shigetoshi Kadota

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38834

7590

05/26/2009

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EXAMINER

KWON, BRIAN YONG S

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

05/26/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/570,252	<b>Applicant(s)</b> KADOTA ET AL.	
	<b>Examiner</b> Brian-Yong S. Kwon	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/02/06</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. Acknowledgement is made of applicant's preliminary amendment filed 11/08/2007.

Claim 1 has been cancelled and claims 2-10 have been added. Claims 2-10 are currently pending for prosecution on the merits.

#### ***Information Disclosure Statement***

2. Enclosed is an initialed copy of PTO 1449 which has been considered for your records.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Guo et al. (AN: 1994:692369, abstract, Chinese Pharmaceutical Journal, 1994, 46(3), 175-83).

Claims 2-4 are drawn to a method of treating or preventing osteoporosis comprising administering a patient with a compound of the formula I or a pharmaceutically acceptable salt or ester thereof whereas claims 5-7 are drawn to a method of inhibiting bone resorption and claims 8-10 are drawn to a method of improving bone formation with the administration of said compound.

With respect to claims 2-7,

The American Heritage Dictionary (Second College Edition, 1982) defines the term “inhibit” as “restrain or hold back; prevent” and “prevent” as “anticipate or counter in advance, to keep from happening”. To the extent that the claims 2-7 encompass methods of preventing

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osteoporosis or inhibiting bone resorption, the instant claims 2-7 are construed to read on any method of treatment employing the administering of the instant claimed compounds as the term “preventing” or “inhibiting” are construed to mean the absolute absence of osteoporosis or bone resorption condition. In other words, the analysis of the instant claims 2-7 allows for the inclusion of any patient population (“a patient”), as long as the same compound is administered to body of the patient in overlapping dosage amounts.

Guo teaches a use of a plant extract derived from *Taxus mairei* containing isotaxiresinol in showing hypoglycemic and antiplatelet activity in animal model, wherein 100mg/kg of isotaxiresinol is administered (abstract).

Although Guo is silent about the activity of said isotaxiresinol in inhibiting bone resorption or preventing osteoporosis, such property or characteristic deems to be inherent to the referenced method of administering same compound in overlapping dosage amount to same patient population, “a patient”. Since the administration of the same compound or composition in overlapping dosage amounts (see the instant dosage amounts that is effective in inhibiting bone resorption and bone formation in Example and Tables 2-4) to “a patient” inherently possessing a therapeutic effect for the same ultimate prophylactic utility as disclosed by the applicant anticipates the claimed invention even absent explicit recitations of the underlying mechanism.

Applicant’s attention is directed to *Ex parte Novitski* 126 USPQ 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such prophylactic utility. In the instant case, as in *Ex parte Novitski*, the claims are directed to preventing a malady or disease with old and well known compounds or compositions. The prior

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art administering compounds inherently possessing a protective utility anticipates claims directed to such protective use.

The fact that the applicant may have discovered a new pharmacological mechanism for said isotaxiresinol of the formula (I) in inhibiting bone resorption or improving bone formation is not considered patentably distinctive over the prior art which are directed to the same prophylactic utility.

With respect to claims 8-10,

Although Guo is silent about the activity of said isotaxiresinol in improving bone formation, such property or characteristic deems to be inherent to the referenced method of administering same compound in overlapping dosage amount to same patient population, "a patient". Since the administration of the same compound or composition in overlapping dosage amounts (see the instant dosage amounts that is effective in inhibiting bone resorption and bone formation in Example and Tables 2-4) to "a patient" inherently possessing a therapeutic effect for the same ultimate purpose as disclosed by the applicant anticipates the claimed invention even absent explicit recitations of the underlying mechanism.

In absence of any indication in the claims 8-10 what patient is being specifically treated, it is considered that the instantly claimed underlying mechanism of said compound in "improving bone formation" is necessary (inherent) feature of the prior art method when the same compound is administered to body of the patient in overlapping dosage amounts. Thus, Guo anticipates the claimed invention.

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### Conclusion

4. No Claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Brian-Yong S Kwon/  
Primary Examiner, Art Unit 1614